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510(k) Summary of Safety and Effectiveness for the
Dall-Miles® System

Proprietary Name:	Dall-Miles® System
Common Name:	Bone Fixation Accessories
Classification Name and Reference	Single/multiple component metallic bone fixation appliances and accessories Title 21 CFR §888.3030 Bone fixation cerclage Title 21 CFR § 888.3010
Regulatory Class:	Class II
Device Product Code(s):	HRS – Plate, fixation, bone LYT – Fixation accessory JDQ – Cerclage, fixation
For Information Contact:	Patricia Setti-LaPerch Regulatory Affairs Associate Stryker Orthopaedics 325 Corporate Drive Mahwah, New Jersey 07430 Phone: (201) 831-5938 Fax: (201) 831-4938 E-Mail: Patricia.LaPerch@stryker.com
Date Summary Prepared:	January 16, 2007

Device Description

The Dall-Miles® product line will now be available with Trochanteric Grip Plates and Trochanteric Grips that facilitate reattachment and fixation of the Greater Trochanter. The Trochanteric Grips will be offered in small, medium, and large sizes. The Trochanteric Grip Plates will be offered in medium sizes ranging from 100-200mm and large sizes ranging from 110-210mm in length. Both the Trochanteric Grips and Grip Plates are compatible with the existing components of the Dall-Miles® System and will be available in Stainless Steel or CoCr alloy materials and packaging options with or without Cables.

Intended Use:

The subject devices are sterile, single use devices. They are intended for use during cemented or cementless primary or revision hip arthroplasty and trochanteric osteotomy. The Stainless Steel alloy Grip and Grip Plates are intended for use with 2.0mm Stainless Steel beaded and non-beaded Cables only. Wrought CoCr alloy Grip and Grip Plates are intended for use with 2.0mm CoCr beaded and non-beaded Cables only. Optional Stainless Steel and Titanium screws are also available for use with the Stainless Steel and Wrought CoCr Grip Plates, respectively.

Indications for Use

- The Dall-Miles® System is indicated for reattachment of the trochanter in any hip procedure using the trochanteric osteotomy (total or partial) approach.

- The Dall-Miles® Trochanteric Grips and Grip Plates are indicated for use in the fixation of the greater trochanter due to trochanteric fracture or osteotomy with intramedullary fixation as the primary device.

- The Dall-Miles® Trochanteric Grip Plate is additionally indicated for use in the fixation of the greater trochanter due to extended trochanteric osteotomies.

Substantial Equivalence:

The Dall-Miles® Trochanteric Grips and Grip Plates are substantially equivalent to the Modified BMP™ Trochanteric Plates, cleared by Biomet (K993510) and the Dall-Miles® Trochanter Cable Super Grip, cleared by Howmedica Osteonics (K962162).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 0 2 2007

Stryker Orthopaedics
% Ms. Patricia Setti-LaPerch
Regulatory Affairs Associate
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K070170
Trade/Device Name: Dall-Miles System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Codes: HRS, LYT, JDQ
Dated: January 16, 2007
Received: January 18, 2007

Dear Ms. Setti-LaPerch:

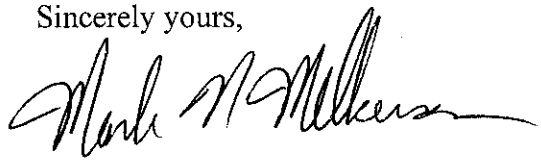
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K070170

Device Name: Dall-Miles® System

Indications for Use

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- The Dall-Miles® Trochanteric Grip Plate is additionally indicated for use in the fixation of the greater trochanter due to extended trochanteric osteotomies.

Prescription Use ___X___ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K07 0170